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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/648,676	05/16/96	LEADER	M 2227-006 EXAMINER

A1M1/0904  
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UNIT	PAPER NUMBER
1102	6

DATE MAILED:

09/04/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7-2-97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or ~~thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1-17 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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Claims 1-3, 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts et al in view of Pace et al '978, Pace '410, Knudson et al, Brown et al or Madou et al.

Betts has been discussed in the previous Office action. Applicant's claims differ by calling for each via through-hole in the substrate to be directly beneath each analyte sensor. Betts shows the through-hole away from the sensor.

Pace '978 shows a conductor via 2 in substrate 3 located directly beneath a sensor 5. See col. 9, lines 31-67. Pace '410 shows a via through-hole 48 in substrate 20 directly beneath a sensor. See col. 7, line 7 to col 8, line 24. Note Pace '410 also shows a cartridge 10 for the sensors and Ca among the analytes (table 1 in col. 12). Knudson shows a via through-hole 120 directly beneath a sensor. See col. 7, line 62 to col. 8, line 13. Brown discloses a via through-hole in substrate 25 directly beneath sensor 27. See col. 6, lines 28-50. Madou discloses a via through-hole in substrate 12 directly beneath a sensor. See col. 4, line 23 to col. 7, line 34; col. 11, line 9 to col. 14, line 6. The use of these secondary references is prompted by applicant's amendment to claim 1, line 8 calling for the through-hole to be directly under a sensor.

It would have been obvious for Betts to locate each via through-hole directly beneath each sensor in view of the secondary references, since the location is matter of design choice. This directly below location is conventional, as shown by the secondary references. Further, there is no unexpected result.

The term "cartridge" is not seen to define over the assembly of Betts. In any event, Pace '410 shows the disposition of a plurality of sensors on a cartridge.

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Claims 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Pace etal '978, Pace '410, Knudson etal, Brown etal or Madou etal and Grubb.

These claims further differ by calling for the internal electrolyte of the reference electrode to be in gel form. As discussed before, Grubb renders a gel electrolyte obvious. It is noted that applicant merely argues that Grubb does not overcome the deficiency of the Betts reference in not showing a via through-hole directly below the sensor. Thus, no separate argument has been presented.

Claims 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Pace etal '978, Pace '410, Knudson etal, Brown etal or Madou etal and Buzza.

These claims further differ by calling for the flow channel to have a dome shape near the oxygen sensor. As discussed before, Buzza renders that obvious. Applicant has not presented a separate argument for this rejection.

Claims 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Pace etal '978, Pace '410, Knudson etal, Brown etal or Madou etal and Buzza and Kuhn etal.

These claims further differ by calling for a hematocrit sensor. As discussed before, Kuhn renders that obvious. Applicant has not presented a separate argument for this rejection.

Claims 1-3, 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace etal '978 in view of Betts etal, Pace '410 or Knudson etal. The citation of Pace etal '978 is prompted by applicant's amendment to line 8 of claim 1

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Pace '978 has been discussed above. Additionally, note that '978 shows a sample flow channel 10 and a reference flow channel 9 defined by an encasement 8. Applicant's claims appear to differ from '978 in that the patent does not seem to show conductive layers on the underside of substrate 3 for providing conductive leads to a measuring instrument.

As discussed before, Betts shows conductive layers on the substrate for providing conductive leads. Pace shows conductive leads 24, 25. See figure 8a and col. 8, line 3. Knudson shows conductive lead 118. See col. 8, line 9.

It would have been obvious for Pace '978 to provide conductive lead layers on the substrate surface in view of the secondary references, since the incorporation of conventional features from analogous prior art is within the skill of the art. Clearly, conductive leads are needed in Pace '978. A conventional location for the leads would be the most obvious location for them.

Claims 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al '978 in view of Betts et al, Pace '410 or Knudson et al and Grubb.

These claims further differ by calling for the gel electrolyte. As discussed before, Grubb shows a gel electrolyte to be well-known. It would have been obvious for Pace '978 to adopt a gel electrolyte, whose viscosity makes the electrode position-insensitive and leak proof.

Claims 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al '978 in view of Betts et al, Pace '410 or Knudson et al and Buzza.

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These claims further differ by calling for an oxygen sensor among the array of sensors. As discussed before, Buzza shows an oxygen sensor. It would have been obvious for Pace '978 to adopt an oxygen sensor, since it is often critical to know the blood oxygen concentration for medical reasons.

Claims 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pace et al '978 in view of Betts et al, Pace '410 or Knudson et al and Buzza and Kuhn et al.

These claims further differ by calling for a hematocrit sensor. As discussed before, Kuhn shows a hematocrit sensor. It would have been obvious for Pace '978 to adopt a hematocrit sensor, since hematocrit value is important medical information.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-32 and claims 1, 3-61 respectively of

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copending Application No. 08/648,675 and 08/649,009 in view of Betts et al. It is noted that applicant apparently intends to file terminal disclaimer(s) to overcome these rejections.

This is a provisional obviousness-type double patenting rejection.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “subminiature” is vague. Contrary to applicant’s assertion, this term is still present at line 7 of claim 1.

Claim 6, line 2, “flow channel with respect to the reference cell” is vague as well as having no antecedent basis. Parent claims 1 and 3 do not recite any flow channel for a reference cell.

Claim 9, line 3 is vague. Does applicant mean the encasement is formed of all three materials together?

Applicant’s reference to copending SN 08/648,694 is noted. However, this application is unavailable for inspection by the examiner at this time. Applicant should point out and maintain a clear line of distinction between ‘694 and the instant application.

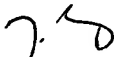
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

The examiner can be reached at 703-308-3329. Any inquiry of a general nature should be directed to the receptionist at 703-308-0661.

  
Ta Tung

Primary Examiner

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